

## **I. REMARKS**

### **A. Status of the Claims**

Claims 1-21, 23-35, 37, 39, and 42 are pending.

### **B. The Claims Are Novel Over Dreher**

Claims 1-5, 9-13, 17-18, and 23-34 are rejected under 35 U.S.C. §102(b) as being anticipated by Dreher (U.S. Patent 5,303,709) as evidenced by Van de Velde (U.S. Patent 5,568,208). Applicants traverse this rejection.

#### ***1. Dreher Does Not Teach All Of the Elements of the Claims***

The Action fails to establish a *prima facie* case of anticipation because it fails to show that Dreher provides any teachings concerning the detection of neovascularized ocular tissue or the diagnosis of an ocular disease involving neovascularization. Dreher does not mention neovascularization nor does it mention ocular diseases involving neovascularization. The Examiner appears to recognize this deficiency, but attempts to gloss over it by generalizing ocular disease involving neovascularization as simply “diseased eyes,” and then arguing that Dreher also discloses “diseased eyes” (Action, p. 4). This is legally impermissible.

While a pending claim is given its broadest reasonable interpretation, this interpretation must be consistent with the specification as it would be understood by a person of ordinary skill in the art. *See* MPEP § 2111. The Examiner’s interpretation of the claims goes well beyond a broad interpretation to the point of completely reading “neovascularization” out of the claims. Moreover, the Examiner’s interpretation is not consistent with the specification. The specification clearly states that “Ocular neovascularization is the formation of new blood vessels in the development of diseases such as, for example, macular degeneration and diabetic retinopathy.” (Specification, para. [0006]). The specification further discloses that such neovascularization occurs in retinal and RPE/choroidal tissue (Specification, para. [0007], [0014]). While it is true that neovascularized eyes are diseased eyes, it is not true that all

diseased eyes are neovascularized. This is evident from Dreher, in which thickening of the nerve fiber layer at the fundus of the eye results in diseased eyes of a different type, *e.g.*, glaucoma (Dreher, col. 3, ln. 61-64).

It is, therefore, clear that Dreher does not provide an anticipating disclosure of all of the elements of any of the current claims. Accordingly, this rejection should be withdrawn.

## **2. *Reflected Light and Backscattered Light***

In the case of reflected light, the *law of reflection* states that the angle at which the wave is incident on the surface equals the angle at which it is reflected. Scattered or diffuse reflections, on the other hand, result when the light is forced to deviate from a straight trajectory by one or more non-uniformities in the medium through which they pass. Backscattered light is a type of scattered light for which the change in the angle of its trajectory is greater than 90°. While it is possible some of the backscattered light will be scattered such that it follows the trajectory of regular reflected light, the backscattered light can be distinguished from the reflected light because the polarization of the backscattered light will be different.

Despite the fact that these are fundamental laws of physics, the Examiner has stated that he disagrees that there is a difference between backscattered light and reflected light (Action, p. 9, Item 8). No factual evidence was provided by the Examiner to support this assertion. If this position is based on the Examiner's personal knowledge, then Applicants request the Examiner provide an affidavit as required under 37 C.F.R. § 1.104(d)(2).

The Examiner's reliance on Dreher's FIG. 1 and FIG. 7 to rebut Applicants' previous arguments is also factually flawed. In particular, the apparatus depicted in FIG. 7 includes pinhole diaphragm 73. As Dreher explains, pinhole diaphragm 73 is included *to eliminate* light not returning from the selected focal plane (col. 7, ln. 29-34). Thus, Dreher is using the pinhole diaphragm to eliminate light coming from deeper within the tissue (*i.e.* light not from the

selected focal plane). To anticipate, a reference must clearly and unequivocally disclose the claimed invention or direct those skilled in the art to the without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083 (Fed. Cir. 2008). In the present rejection, however, the Examiner as picked elements from various disclosures in Dreher (e.g., FIGs. 1 and 7) without regard to the incompatibilities of these disclosures.

### **C. The Rejections Under 35 U.S.C. §103(a) Are Overcome**

#### **1. Dreher in View of Glaser or Larrick**

Claims 6-8 and 14-16 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Dreher *et al.* (U.S. Patent 5,303,709) in view of Glaser *et al.* (U.S. Patent 5,767,079) or Larrick *et al.* (U.S. Patent 5,670,151). Applicants respectfully traverse.

As discussed above, Dreher does not provide any teachings concerning the detection of neovascularized ocular tissue or the diagnosis of an ocular disease involving neovascularization. Rather, the Examiner has taken the legally impermissible approach of reading “neovascularization” out of the claims. Furthermore, although Glaser and Larrick are cited as teaching methods of treating or controlling ophthalmic disorders associated with neovascularization, such teachings do nothing to cure the deficiencies in Dreher. There is still no teaching or suggestion concerning the detection of neovascularized ocular tissue or the diagnosis of an ocular disease involving neovascularization.

Moreover, disclosures in Dreher teach away from the presently claimed invention and fail to provide a reasonable expectation of success in achieving the claimed invention. For example, and as discussed above, the apparatus depicted in Dreher’s FIG. 7 includes pinhole diaphragm 73 that is used to eliminate light not returning from the selected focal plane (col. 7, ln. 29-34), thus eliminating much of the backscattered light. Additionally, Dreher teaches “discarding any data,

that is any light rays, that are returning from the eye having altered polarization.” (Dreher, col. 7, ln. 24-26). Dreher further states that “the confocal topographical mapping technique can be enhanced by discarding all light information in which the light rays have been altered in their polarization state.” (Dreher, col. 7, ln. 43-46). As discussed above, backscattered light would have an altered polarization and would, therefore, be discarded according to these teachings.

Although Dreher does mention detecting light with an altered polarization state in some circumstances (*see e.g.*, col. 7, ln. 50-53), there is no teaching that this information could be used to detect neovascularization nor is there any guidance of when or how to do so. Accordingly, a person of ordinary skill in the art would not have had a reasonable expectation of success in achieving the claimed invention. A reasonable expectation of success is required to establish a *prima facie* case of obviousness. MPEP § 2143.02.

In view of the above, claims 6-8 and 14-16 are patentable over Dreher, Glaser, and Larrick. Applicants, therefore, request the withdrawal of this rejection.

## **2. Dreher in View of Hay**

Claim 19 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Dreher in view of Hay (U.S. 5,632,282). Applicants traverse.

Claim 19 recites a data acquisition system configured to measure a polarization shift of a light beam backscattered off of a tissue sample in the holder and diagnose an ocular disease if the measured polarization shift corresponds to a polarization shift of a neovascularized tissue. As discussed above, Dreher does not provide any teachings concerning the detection of neovascularized ocular tissue or the diagnosis of an ocular disease involving neovascularization. Thus, regardless of whether it would have been obvious to modify the teachings of Dreher to include a chinrest as described by Hay, the combination would still fail to render obvious claim 19. Applicants, therefore, request the withdrawal of this rejection.

### **3. Dreher in View of Hay and Trachtman**

Claims 20-21, 35, 37, 39, and 42 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Dreher in view of Hay and further in view of the Trachtman patent (U.S. 5,002,384). Applicants traverse.

As discussed above, Dreher does not provide any teachings concerning the detection of neovascularized ocular tissue or the diagnosis of an ocular disease involving neovascularization. Hay's disclosure of a chinrest does nothing to overcome this deficiency in Dreher. Trachtman describes using infrared light to monitor a patient's eye position. Trachtman's objective is to train a patient to achieve a level of proficiency in the voluntary control of eye position (*see* Abstract). Trachtman does not even mention neovascularization, much less provide any teachings regarding methods or apparatuses for its detection and diagnosis. Accordingly, Trachtman does not overcome the above-mentioned deficiencies in Dreher and Hay.

In view of the foregoing, there is no *prima facie* case of obviousness of claims 20-21, 35, 37, 39, and 42 under 35 U.S.C. §103(a) based on the Dreher patent and the Hay patent in view of the Trachtman patent. Therefore, it is respectfully requested that the rejection of these claims be withdrawn.

**D. Conclusion**

In view of the foregoing, it is respectfully submitted that each of the pending claims is in condition for allowance. The Examiner is invited to contact the undersigned attorney at (512) 536-5654 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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